

## **REMARKS**

### **I. Status of the Application.**

Claims 1-9 and 12-22 were pending in the Application as of the date of the Final Office Action. In the Final Office Action, the Examiner:

(a) rejected claims 1-9 and 12-22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement;

(b) rejected claims 1-4, 9, 12-16, 18, 20, and 22 under 35 U.S.C. § 102(b) as allegedly being anticipated by U.S. Patent No. 5,645,834 to Cockrum ("Cockrum"); and

(c) rejected claims 5-8, 17, 19 and 21 under 35 U.S.C. § 103(a) as allegedly being obvious over Cockrum in view of International Patent Application Publication No. WO 97/16977 of inventor Antony Scammell ("Scammell") and U.S. Patent No. 5,147,548 to Heis et al. ("Heis").

In this Response, Applicant respectfully cancels claim 20 and submits the following remarks. Applicant respectfully submits that the following remarks herein traverse or overcome the Examiner's rejections to the claims of the present Application, and that claims 1-9, 12-19, 21, and 22 are in a condition for allowance.

### **II. No New Matter Is Introduced by Way of Amendment.**

Applicant respectfully submits that no new matter has been introduced by way of the present remarks and by canceling claim 20. Accordingly, Applicant respectfully requests that claims 11-9, 12-19, 21 and 22 of the Application proceed to allowance for the reasons provided herein.

**III. The Rejection of Claims 1-9 and 12-22 Under 35 U.S.C. § 112, First Paragraph, is Overcome and Should be Withdrawn.**

In the Final Office Action, the Examiner rejected claims 1-9 and 12-22 under 35 U.S.C. § 112, first paragraph, as allegedly failing to comply with the written description requirement. In the rejection, the Examiner alleged that "[t]he process steps of lowering a temperature of the filtered colostrum so that the filtered colostrum is frozen or highly refrigerated, and sterilizing the filtered colostrum at the lower temperature are not supported by the original disclosure at the time the claimed invention was made." Final Office Action, page 2. Applicant respectfully disagrees for at least the following reasons.

Applicant respectfully submits that the two aforementioned claim elements, which appear in each of Applicant's independent claims 1, 4, and 9, have direct support in paragraph [0008] of the present Application. As stated therein with respect to the applicable example, "[t]he filtered colostrum is packaged in containers and frozen," and that "the sterilization takes place on frozen or highly refrigerated colostrum, to prevent or minimize denaturation." Application, paragraph [0008]. As such, Applicant respectfully submits that there is direct support for the claim elements of lowering the temperature of the colostrum and sterilizing the colostrum at that lower temperature as referenced in paragraph [0008] of the present Application.

The Examiner also alleged that "the lowering of the temperature to minimize denaturation" is also not supported by the original disclosure. Final Office Action, page 2. Applicant again respectfully disagrees, as paragraph [0008], as previously referenced, states that "sterilization takes place on frozen or highly refrigerated colostrum, *to prevent or minimize denaturation.*" Application, paragraph [0008], emphasis added. Accordingly, Applicant

respectfully submits that there is direct support for the aforementioned element appearing in Applicant's claim 19.

The Examiner further alleged that the original disclosure did not support the step of sterilizing the colostrum without centrifugation as claimed in claim 20. In attempt to further prosecution of the present Application, Applicant cancels claim 20, rendering that particular claim rejection moot.

Accordingly, and for the foregoing reasons, Applicant respectfully submits that the rejection of claims 1-9 and 12-22 under 35 U.S.C. § 112, first paragraph, is overcome and should be withdrawn.

**IV. The Rejection of Claims 1-4, 9, 12-16, 18, 20 and 22 under 35 U.S.C. § 102(b) as Allegedly Being Anticipated by Cockrum is Overcome and Should be Withdrawn.**

In the Office Action, the Examiner rejected claims 1-4, 9, 12-16, 18, 20 and 22 under 35 U.S.C. § 102(b) as allegedly being anticipated by Cockrum. A rejection under 35 U.S.C. § 102(b) can be overcome by "persuasively arguing that the claims are patentably distinguishable from the prior art." MPEP § 706.02(b). Applicant respectfully submits that the rejection of claims 1-4, 9, 12-16, 18, 20 and 22 is overcome and should be withdrawn because claims 1-4, 9, 12-16, 18, 20 and 22 are patentably distinguishable over Cockrum, and because Cockrum does not teach (expressly or inherently) all of the limitations of any of these claims as would be required by MPEP § 2131 to support an anticipation rejection. At a minimum, for instance, Cockrum fails to teach any method of preparing sterile highly filtered colostrum as claimed in

Applicant's independent method claims 4 and 9 or a sterile bovine colostrum composition prepared as described in claims 1-4.

A prior art patent, publication, or event is for the same "invention," as that word is used in 35 U.S.C. § 102, and therefore anticipating, if the prior art patent, publication or event discloses each and every limitation found in the claims, either expressly or inherently. *Rockwell Intern. Corp. v. U.S.*, 147 F.3d 1358, 1363 (Fed. Cir. 1998); *Electro Med Sys. S.A. v. Cooper Life Sciences*, 34 F.3d 1048, 1052 (Fed. Cir. 1994). "[A] claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference." MPEP § 2131.01. Omission of any claimed element, no matter how insubstantial, is grounds for traversing a rejection based on 35 U.S.C. § 102. *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983).

In the Office Action, the Examiner references col. 3, lines 50-55 of Cockrum, which refers to an injectable colostrum. However, the preceding portion (lines 25-50 of col. 3 of Cockrum), identified as "PREPARATION OF COLOSTRUM," clearly identifies the following steps:

- (a) obtain and freeze colostrum (Cockrum, col. 3, lines 26-28);
- (b) thaw the colostrum for 8-24 hours (presumably to ambient/room temperature) (Cockrum, col. 3, lines 28-31);
- (c) add calcium chloride and microbial rennet (Cockrum, col. 3, lines 32-35);
- (d) agitate the mixture and heat to 85°F to cause coagulation (Cockrum, col. 3, lines 36-37);

- (e) cut the curd to allow the fat to float above the curd and produce a whey underneath (Cockrum, col. 3, lines 38-39);
- (f) filter the whey and pass it through a cream separator (Cockrum, col. 3, lines 42-44);
- (g) refrigerate the resultant product (Cockrum, col. 3, lines 44-45);
- (h) filter and reduce the resultant product's volume (Cockrum, col. 3, lines 45-46);
- (i) adjust the pH using sodium hydroxide (Cockrum, col. 3, lines 46-49);
- (j) dilute the resultant product with physiological saline (Cockrum, col. 3, lines 49-50); and
- (k) filtering the resultant product again for administration to calves (Cockrum, col. 3, lines 50-51).

Applicant respectfully submits that as shown above, the method of Cockrum clearly includes the use of calcium chloride, rennet, agitation, heating, presumably hot filtering, cream separation, refrigeration, additional filtering and volume reduction, pH adjustment, dilution with saline, and additional filtering, which is clearly a different method than is claimed in pending claims 1, 4, and 9. Conversely, and as claimed in Applicant's claims 1, 4 and 9, Applicant's colostrums are prepared by performing the steps of filtering, lowering the temperature, and sterilizing at the lower temperature, whereby said methods are clearly not taught by or disclosed in Cockrum, noting that the method of Cockrum included at least ten separate steps (as noted above) in order to obtain a resultant product for administration.

Accordingly, Applicant respectfully submits that Cockrum does not disclose, teach, or suggest Applicant's methods as claimed in independent claims 4 and 9 or Applicant's sterile bovine colostrum prepared in accordance with independent claim 1. As such, Cockrum does not disclose each and every element of the claims of the present invention, and Applicant respectfully submits that claims 1, 4, and 9 are allowable, and the rejection of claims 1, 4, and 9 under 35 U.S.C. § 102(b) as being anticipated by Cockrum is overcome and should be withdrawn.

Claims 2, 3, 12-16, 18, and 22 depend from and includes all the limitations of claims 1 and 9, and, as discussed above, claims 1 and 9 are believed to be allowable over Cockrum. Therefore, it is respectfully submitted that claims 2, 3, 12-16, 18, and 22 are also allowable, and Applicant respectfully requests that the rejection of claim claims 2, 3, 12-16, 18, and 22 as being anticipated by Cockrum is also overcome and should be withdrawn.

V. **The Rejection of Claims 5-8, 17, 19 and 21 Under 35 U.S.C. § 103(a) as Allegedly Being Obvious Over Cockrum in View of Scammell and Heis is Overcome and Should be Withdrawn.**

Applicant respectfully submits that the rejection of claims 5-8, 17, 19 and 21 under 35 U.S.C. § 103(a) is overcome and should be withdrawn because Cockrum, Scammell, and Heis, either alone or in view of one another, do not disclose all of the limitations of independent claims 1, 4, and 9, for which rejected claims 5-8, 17, 19, and 21 are dependent therefrom.

As required under *Graham v. John Deere Co.*, the first steps in determining obviousness is to determine the scope and content of the prior art and ascertain the differences between the prior art and the claims at issue. 383 U.S. 1, 17-18 (1966). "In determining (such) differences

between the prior art and the claims, the question under 35 U.S.C. 103 is not whether the differences themselves would have been obvious, but whether the claimed invention as a whole would have been obvious." MPEP § 2141.02. In addition, the teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on the applicant's disclosure. MPEP § 2143 (citing *In re Vaeck*, 947 F.2d at 493).

Applicant respectfully disagrees with the rejection of claims 5-8, 17, 19 and 21 for at least the reason that Cockrum, Scammell, and Heis do not teach, disclose, or suggest Applicant's methods as claimed in independent claims 4 and 9 or Applicant's sterile bovine colostrum prepared in accordance with independent claim 1. As referenced in Section IV above, Applicant has demonstrated that Cockrum does not anticipate independent claims 1, 4, and 9 of the present Application, and that claims 1, 4, and 9 are allowable in view of Cockrum. The references cited within the rejection under 35 U.S.C. 103(a), with respect to Scammell and Heis in particular, also do not teach, disclose, or suggest Applicant's methods as claimed in independent claims 4 and 9 or Applicant's sterile bovine colostrum prepared in accordance with independent claim 1.

Therefore, and consistent with the foregoing, Applicant respectfully submits that all of the elements and limitations of independent claims 1, 4, and 9, and each claim dependent therefrom, are not disclosed by combining Cockrum, Scammell, and Heis. As such, Applicant respectfully submits that there is no *prima facie* case of obviousness in view of Cockrum, Scammell, and Heis with respect to any pending claim of the present Application. Accordingly, and at least for the reasons stated above, Applicant respectfully submits that the rejections of

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claims 5-8, 17, 19 and 21 under 35 U.S.C. § 103(a) over Cockrum in view of Scammell and Heis  
is overcome and should be withdrawn.



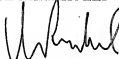
**CONCLUSION**

For all the foregoing reasons, it is respectfully submitted that Applicant has made a patentable contribution to the art and that this response places the Application in condition for allowance. Accordingly, favorable reconsideration and allowance of claims 1-9, 12-19, 21, and 22 of this Application is respectfully requested.

In the event Applicant has inadvertently overlooked the need for a payment of a fee or extension of time, Applicant conditionally petitions therefor, and authorizes any fee deficiency to be charged to deposit account 09-0007. When doing so, please reference the above-listed docket number.

Respectfully submitted,

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